

Remarks

Reconsideration of this Application is respectfully requested.

Upon entry of the foregoing amendments, claims 47, 49, 51-63, 107 and 111-118 are pending in the application, with claim 47 being the independent claim. Claims 47, 49, 53-57, 60, 107, 112 and 114 have been amended. Claims 48, 50, 106 and 108-110 have been canceled. New claims 117 and 118 have been added. Support for the claim amendments and new claims may be found in the original claims and throughout the specification, for example at page 7, lines 8-27. No new matter is added to the present application by the foregoing amendments, which are fully supported in the specification as originally filed.

Based on the above amendments and the following remarks, Applicants respectfully request that the Examiner reconsider all outstanding objections and rejections and that they be withdrawn.

Objections to the Specification

The Examiner objects to the use of the trademarks SuperScriptTM, SuperScriptTM II, ThermoScriptTM and ThermoScriptTM II, stating that they should be capitalized wherever they appear and be accompanied by their generic terminology. The specification and Claim 114 have been amended to provide these terms in capital letters, and to include their generic terminology.

The specification was also objected to as improperly incorporating documents by reference. It was alleged that the application should specify what specific language applicant seeks to incorporate by reference, and where this information is to be found in each of the cited documents. Applicants respectfully traverse the objection.

The Examiner cites *Advanced Display Systems, Inc. v. Kent State University* for the proposition that "[t]o incorporate by reference, the host document must identify with detailed particularity what specific material it incorporates and clearly indicate where that material is found in the various documents." While the Court in *Advance Display Systems* did put forth such a standard with regard to incorporation by reference, a careful reading of the case *in toto* shows that the standard in *Advance Display Systems* is limited to an *anticipation determination* and is not the standard for a 35 U.S.C § 112, first paragraph determination. Specifically, the court in *Advance Display Systems* states that "Incorporation by reference provides a method for integrating material from various documents into a host document--a patent or printed publication *in an anticipation determination*--by citing such material in a manner that make clear that the material is effectively part of the host document" (emphasis added). *Advanced Display Systems, Inc. v. Kent State University*, 54 USPQ2d 1673, 1679.

However, the MPEP states in relevant part:

[M]ere reference to another application, patent, or publication is not an incorporation of anything therein into the application containing such reference for the purpose of the disclosure by 35 U.S.C. § 112, first paragraph. *In re Seversky*, 474 F.2d 671, 171 USPQ 144 (CCPA 1973)... Particular attention should be directed to specific portions of the reference document where the subject matter being incorporated may be found. MPEP § 608.01(p).

Thus, the standard for a proper incorporation by reference put forth in *Advance Display Systems*, which is limited to an anticipation determination, and the standard set forth in the MPEP regarding 35 U.S.C § 112, first paragraph, are distinct and separate standards. As such, the Examiner is in error when citing *Advance Display Systems* for the proper standard in determining whether an incorporation by reference is proper for the purposes of 35 U.S.C § 112, first paragraph.

In addition, the MPEP notes a distinction between "essential material," that which is necessary to (1) describe the invention, (2) provide an enabling disclosure of the claimed invention, or (3) describe the best mode, and "non-essential subject matter," which is subject matter referred to for purposes of indicating the background of the invention or illustrating the state of the art. MPEP § 608.01(p). Thus, different types of subject matter have distinct incorporation by reference requirements. The Examiner has failed to indicate what type of material is the basis for the present objection.

Accordingly, it is the Applicant's position that the Examiner's objection is in error because (1) the incorrect standard for a proper incorporation by reference has been asserted and (2) the Examiner has failed to particularly point out the specific material that is allegedly improperly incorporated by reference. Applicant respectfully requests that the Examiner either provide such specificity regarding the objection or withdraw the objection completely.

Applicants therefore respectfully request withdrawal of the objections to the specification.

Claim objection

Claim 106 was objected to as not further limiting claim 47 from which it depends. Claim 106 has been canceled, thus obviating this objection.

Applicants therefore respectfully request withdrawal of the claim objection.

Rejections under 35 U.S.C. § 112, first paragraph (written description)

Claims 47-63 and 106-116 were rejected under 35 U.S.C. § 112, first paragraph as failing to comply with the written description requirement. The Office Action states that although the use of any "inhibitor" of reverse transcriptase activity is recited in claim 47, only

antibody inhibitors are disclosed in the specification. Claim 47 as amended recites antibody or antibody fragment inhibitors, thus obviating this portion of the rejection. Additionally, claims 106 and 108-110 have been canceled, thus obviating this rejection with regard to claims 106 and 108-110.

In addition, the Office Action alleges that claim 47 places no upper or lower limit on the temperature under which the assay is performed, and that the disclosure does not provide an adequate written description to support this scope. Claim 47 as amended recites that the template, polypeptide and inhibitor are incubated at a temperature between 10°C and 90°C. This temperature range is described in the specification at page 5, lines 24-26. Dependent claims 54-56 as amended, and new dependent claim 117, recite particular temperatures within this range, all of which are clearly disclosed in the present specification at page 7, lines 15-17.

Thus, the written description requirement of 35 U.S.C. § 112, first paragraph, is fully satisfied for the subject matter of the present claims. Applicants assert that the claimed invention is sufficiently described in the disclosure such as to reasonably convey to one skilled in the relevant art that Applicant had possession of the claimed invention at the time the application was filed.

In view of the amendments and comments presented above, Applicants respectfully request withdrawal of the rejection under 35 U.S.C. § 112, first paragraph.

Rejections under 35 U.S.C. § 112, first paragraph (enablement)

Claims 47-63 and 106-116 were rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the enablement requirement. In particular, the Office Action alleges that “that the specification fails to set forth a reproducible procedure where an inhibitor of RT

activity was used where the inhibitor was anything other than an antibody. Further, the specification does not set forth a reproducible procedure whereby the assay was conducted under any temperature and where the RT has significant RNase H activity.” Claims 106 and 108-110 have been canceled, thus obviating this rejection with regard to claims 106 and 108-110.

With regard to the inhibitor portion of the rejection, the claims as amended specify antibody or antibody fragment inhibitors, thus obviating this portion of the rejection. Regarding the temperature portion of the rejection, claim 47 as amended recites that the assay is performed between 10°C and 90°C. One of ordinary skill in the art, using the protocols provided in the present specification, could easily determine the ability of an antibody or antibody fragment inhibitor of a reverse transcriptase to inhibit the reverse transcriptase at any temperature within this range without undue experimentation.

Regarding the concern about the performance of assays where reverse transcriptases have significant RNase H activity, the specification clearly sets forth that reverse transcriptases suitable for use in the present invention need not be RNase H⁻ RTs. While the use of RNase H⁻ RTs is a preferred embodiment, such an RT is not essential for practicing the claimed invention. The specification at page 22, lines 23-29, identifies reverse transcriptases that are not RNase H⁻, and that are suitable for the invention. The specification at page 22, line 29, to page 23, line 1, states that “[I]n a further preferred embodiment, the reverse transcriptases are reduced or substantially reduced in RNase H activity.” One of ordinary skill in the art would realize that the present method would work regardless of whether the RT had or lacked RNase H activity. The skilled artisan could easily determine the ability of any RT, either having or lacking RNase H activity, to work in the claimed methods using the methods disclosed in the present specification without undue experimentation.

In view of the amendments and comments presented above, Applicants respectfully request reconsideration and withdrawal of the rejection under 35 U.S.C. § 112, first paragraph.

Rejections under 35 U.S.C. § 112, second paragraph

Claim 114 was rejected as indefinite as the result of the use of trademarks. Claim 14 as amended provides the generic terminology as requested by the Examiner. Thus, reconsideration and withdrawal of the rejection under 35 U.S.C. § 112, second paragraph is respectfully requested.

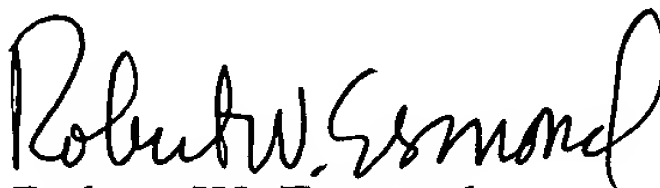
Conclusion

All of the stated grounds of objection and rejection have been properly traversed, accommodated, or rendered moot. Applicants therefore respectfully request that the Examiner reconsider all presently outstanding objections and rejections and that they be withdrawn. Applicants believe that a full and complete reply has been made to the outstanding Office Action and, as such, the present application is in condition for allowance. If the Examiner believes, for any reason, that personal communication will expedite prosecution of this application, the Examiner is invited to telephone the undersigned at the number provided.

Prompt and favorable consideration of this Amendment and Reply is respectfully requested.

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.



Robert W. Esmond
Attorney for Applicants
Registration No. 32,893

Date: March 17, 2005

1100 New York Avenue, N.W.
Washington, D.C. 20005-3934
(202) 371-2600